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or Individual Name	Cathy A. Kodroff	i							
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of) Group Art Unit:
Andersen et al) Examiner:
Appln. No. 10/617,038)
Filed: July 11, 2003) HAND-DELIVERED
For: THERAPEUTIC TB VACCINE) November 26, 2003
Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450	

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicant submits to the Examiner the attached Form PTO/SB/08A/B document listing and this paper pursuant to 37 CFR § 1.56 and § 1.97-1.98. Form PTO/SB/08A/B are attached and a copy of the documents are enclosed herewith. This Information Disclosure Statement is submitted more than three months from the filing date of this application and before the receipt of a first Office Action on the merits. Therefore, no fees are believed due.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees to our Deposit Account Number 08-3040.

REMARKS

Listed below are previously filed, co-pending, related U.S. patent applications. These applications and the present application are commonly owned: Copies of applications and claims are enclosed.

- (1) U.S. Patent Application No. 09/310,551, filed May 12, 1999, US Patent No. 6,649,170, issued on November 18, 2003 US Patent Application No. 10/654,720, filed September 3, 2003
- (2) U.S. Patent Application No. 10/217,787, filed August 13, 2002, publication No. US-2003-0036638-A1, February 20, 2003

The Examiner is respectfully requested to consider the enclosed documents identified in this paper and in the attached Form PTO/SB/08A/B during the course of examination of this application.

Respectfully submitted,

HOWSON AND HOWSON Attorneys for Applicant

By

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Registration No. 33,980

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		OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No.¹ Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), columeous number(s), publisher, city and/or country where published									
	D	SAMBROOK ET AL, molecular cloning, A laboratory manual, Cold Spring Harbor Laboratories, NY, (1989) XP-002091112								
	E	Anon. Global Tuberculosis Control, WHO Report. (2001)								
	F	BRANDT ET AL, ESAT-6 Subunit Vaccination against Mycobacterium Tuberculosis, Infection and Immunity, Vol. 68, No. 2, pp. 791-795 (Feb. 2000)								
	G	BOON ET AL, Journal of Bacteriology, Vol. 183, No. 8 pp. 2672-2676, (April 2001)								
	Н	DOHERTY ET AL, Immune Responses to the Mycobacterium Tuberculosis-Specific Antigen ESAT-6 Signal Subclinical Infection among Contacts of Tuberculosis Patients, Journal of Clinical Microbiology, Vol. 40, No. 2, pp. 704-706, (February 2002)								
	I	FLORCZYK ET AL, Identification and Characterization of Mycobacterial Proteins Differentially Expressed under Standing and Shaking Culture Conditions, Including Rv2623 from a Novel Class of Putative ATP-Binding Proteins, Infection and Immunity, Vol. 69, No. 9, pp. 5777-5785, (September 2001)								
	J	HARBOE ET AL, B-Cell Epitopes and Quantification of the ESAT-6 Protein of Mycobacterium Tuberculosis, Infection and Immunity, Vol. 66, No. 2, pp. 717-723, (February 1998)								
	K	MANGANELLI ET AL, The Mycobacterium Tuberculosis ECF Sigma Factor σ ^E : Role in Global Gene Expression and Survival in Macrophages, Molecular Microbiology, Vol. 41, No. 2, pp. 423-437, (May 2001)								
	L	MONAHAN ET AL, Differential Expression of Mycobacterial Proteins Following Phagocytosis by Macrophages, Microbiology, 147, pp. 459-471, (2001)								
Examiner Signature		Date Considered								

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. this collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the Individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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	Group Art Unit						
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Sheet 3 of 3	Attorney Docket Number	SSI5AUSA					

		OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), columeousse number(s), publisher, city and/or country where published	T ²
	M	RAVN ET AL, Human T Cell Responses to the ESAT-6 Antigen from Mycobacterium Tuberculosis, The Journal of Infectious Diseases, 179, pp. 637-45, (1999)	
	N	ROSENKRANDS ET AL, Identification an Characterization of a 29-Kilodalton Protein from Mycobacterium Tuberculosis Culture Filtrate Recognized By Mouse Memory Effector Cells, Infection and Immunity, Vol. 66, No. 6, pp. 2728-2735, (June 1998)	
	0	ROSENKRANDS ET AL, Hypoxic Response of Mycobacterium Tuberculosis Studied by Metabolic Labeling and Proteome Analysis of Cellular and Extracellular Proteins, Journal of Bacteriology, Vol. 184, No. 13, pp. 3485-3491, (July 2002)	
	P	SHERMAN ET AL, Regulation of the Mycobacterium Tuberculosis Hypoxic Response Gene Encoding α-Crystallin, PNAS, Vol. 98, No. 13, pp. 7534-7539, (June 19, 2001)	
	Q	SKJØT ET AL, Comparative Evaluation of Low-Molecular-Mass Proteins form Mycobacterium Tuberculosis Identifies Members of the ESAT-6 Family as Immunodominant T-Cell Antigens, Infection and Immunity, Vol. 68, No. 1, pp. 214-220, (January 2000)	
	R	VORDERMEIER ET AL, Correlation of ESAAT-6- Specific Gamma Interferon Production with Pathology in Cattle Following Mycobacterium Bovis BCG Vaccination against Experimental Bovine Tuberculosis, Infection and Immunity, Vol. 70, No. 6, pp. 3026-3032, (June 2002)	
Examiner Signature		Date Considered	<u> </u>

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